**BEFORE THE**
**ADMINISTRATIVE HEARING COMMISSION**
**STATE OF MISSOURI**

| | | |
|---|---|---|
| **MISSOURI BOARD OF PHARMACY** | ) | |
| Petitioner, | ) | |
| v. | ) | **No. 10-0519 PH** |
| **LEE ORI** | ) | |
| **And** | ) | |
| **LEE ORI d/b/a SPECIALTY PHARMACY OF ST. LOUIS, LLC** | ) | |
| Respondent. | ) | |

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY, LEE ORI AND LEE ORI D/B/A SPECIALTY PHARMACY OF ST. LOUIS, LLC.**

Lee Ori, Specialty Pharmacy of St. Louis, LLC and the State Board of Pharmacy ("Board") enter into this settlement agreement for the purpose of resolving the question of whether Lee Ori's license as a pharmacist and the pharmacy license for Specialty Phamacy of St. Louis, LLC. will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo 2000, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Lee Ori and Specialty Pharmacy of St.Louis, LLC acknowledges that each understands the various rights and privileges afforded each by law, including the right to a hearing of the charges against each; the right to appear and be represented by legal counsel; the right to have all charges against each proven upon the record by competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against each; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against each and, subsequently, the right to a disciplinary hearing before the Board at which time each may present evidence in mitigation of discipline; and the right to seek attorney's fees incurred in defending the Board's action against each's license.

Being aware of these rights provided to each by operation of law, Lee Ori and Specialty Pharmacy of St. Louis, LLC knowingly and voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to each.

Lee Ori and Specialty Pharmacy of St. Louis, LLC acknowledges that each has received a copy of the investigative report, and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulations that the Board believes were violated. Solely for the purpose of settling this dispute, and for no other purpose, each stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Ori's license as a pharmacist, license number 2000148445, and pharmacy license number 2003001140 for Specialty Pharmacy of

St. Louis, LLC is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo, as amended.

The parties agree that this Settlement Agreement and any statements or stipulations contained herein should not be used for or constitute and admission for any purpose other than to settle the Disputes between the parties, pursuant to applicable law, including *State ex rel. Melahn v. Huesemann,* 942 S.W.2c 424 (Mo.App. W.D. 1997). It is not the intention of the parties that the statements and stipulations herein be used for any other purpose than settling the disputes between the parties.

**Joint Stipulation of Facts and Conclusions of Law**

1. The Missouri Board of Pharmacy is an agency of the State of Missouri created and established pursuant to § 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Lee Ori d/b/a Specialty Pharmacy of St. Louis, LLC (Specialty) was permitted by the Board as a pharmacy, permit number 2003001140. Specialty's permit was current and active at all times material herein. Specialty surrendered its permit in connection with transfer of ownership of the pharmacy on or about October 30, 2009.

3. Specialty was located at 623 North New Balance Road, St. Louis, Missouri.

4. Custom Mediations of St. Louis (Custom) was permitted by the Board as pharmacy, permit number 2006029910. Custom permit was current and active at all times material herein prior to January 20, 2008. Custom closed its operations on January 20, 2008.

5. Custom was located at 633 North New Balance Road, St. Louis, Missouri, immediately adjacent to Specialty Pharmacy.

6. Lee Ori is licensed by the Board as a pharmacist, license number 2000148445. Ori's license is and was current and active at all times material herein.

7. Ori served as pharmacist-in-charge of both Specialty and Custom at all times material herein.

8. Custom's permit included Class J shared services authority.

Compounding other than pursuant to individual patient prescription

9. Prior to Custom closing, part of its routine practice included compounding prescriptions for a fat dissolving drug.

10. When Custom Medications submitted its application for licensure, Ori represented that the facilities it was sharing services with were licensed with the Missouri Board of Pharmacy and maintained a class J status on their license. At that time, this was accurate.

> However, subsequent to that time, and during parts of this period, Ori and other Custom staff compounded and shipped this drug in bulk to pharmacies in Arizona and Nevada, in anticipation of these pharmacies filing prescriptions presented to such pharmacies.

11. Customs shipment of bulk compounded product to the Nevada and Arizona pharmacies was not part of a valid shared services practice in that neither the Arizona nor Nevada pharmacies held a Missouri Class J license.

12. Pursuant to 20 CSR 2220-2.650(1)(A)3 each location involved in providing shared services must maintain separate licenses.

Use of unlicensed facility

13. On or about May 22, 2008, Specialty and its staff used Custom's facility to prepare sterile compounds for dispensing by Specialty.

14. On or about May 22, 2008, two large plastic totes containing compounded Deoxycholic Acid Injection, lot 04200822@25 were present at the Custom facility.

15. The lot was compounded pursuant to Specialty's authority.

16. These acts constitute the practice of pharmacy at Custom's unlicensed facility.

17. Section 338.210 provides in pertinent part:

> 1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:
>
> (1) Where the practice of pharmacy is offered or conducted;
>
> (2) Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;
>
> (3) Where the words "pharmacist", "apothecary", "drugstore", "drugs", and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;
>
> (4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.
>
> 2. All activity or conduct involving the practice of pharmacy as it relates to an identifiable prescription or drug order shall occur at the pharmacy location where such identifiable prescription or drug order is first presented by the patient or the patient's authorized agent for preparation or dispensing, unless otherwise expressly authorized by the board.

18. Section 338.220 provided in pertinent part:

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy.

Misbranded, outdated, and inappropriately maintained drugs

19. On or about May 22, 2008, the following drugs were detemined, based upon a physical inspection of the containers, to have been misbranded or outdated drugs which were not separated from Specialty's inventory:

| Drug | Lot number | Expiration Date | Issue |
|---|---|---|---|
| Methocel E4M | C106666<br>C118051 | 7/19/05<br>6/19/08 | Bears two lot numbers and expiration dates |
| Avicel Microcrystalline Cellulose NF | C106605<br>C120208 | 6/09/07<br>12/5/10 | Bears two lot numbers and expiration dates |
| Levamisole 50mg Capsule | 12200714@12<br>07200718@13 | 6/11/08<br>1/14/08 | Bears two lot numbers and expiration dates |
| Base PCCA Polyglycol Troche | 1076661<br>1438752 | 6/20/09<br>9/13/10 | Bears two lot numbers and expiration dates |
| Methylcobalamin 25000 mcg/ml Injection | 122006513@12 | | No expiration date |
| 4 oz bottle of liquid | | | No label |
| Bag containing red solution | | | No label |
| Oyst-Cal D Caps 500 | | | No lot number or expiration date |
| Pluronic 30% Gel | 02200409:66@7 | 8/7/04 | Outdated |
| Magnesium Stearate NF | C105710 | 9/12/05 | Outdated |
| Pluronic Gel 20% | 746179 | 4/25/06 | Outdated |
| Urea USP | C108014 | 6/30/07 | Outdated |
| Melatonin Trituration | 01299814@28 | 1/14/08 | Outdated |
| Melphalan In | 01200822@17 | 2/5/08 | Outdated |

| | | | |
|---|---|---|---|
| Lipoderm 0.75mg/0.2ml | | | |
| Oxytocin/Sorbitol Triturate | 09200713@17 | 3/11/08 | Outdated |
| Interferon Alpha 30,000 IU/ml | 12200726@7 | 3/25/08 | Outdated |
| Dexamethasone 1mg/ml Suspension | 02200828@14 | 3/29/08 | Outdated |
| Budesonide Chicken 1mg Treat | 03200806@05 | 4/5/08 | Outdated |
| Phentolamine Mesylate 5mg/35 Mann Trit. | 02200806@4 | 5/6/08 | Outdated |
| Terbutaline Sulfate Injection | 18777@1 | 5/18/08 | Outdated |
| Alprostadil 100mg/ml | 04200821@11 | 5/21/08 | Outdated |
| Undecylenic Acid USP | C122064 | 4/30/10 | Repackaged with greater than 1 year expiration date |

20. 20 CSR 2220-2.010(6) as effective stated in pertinent part:

> Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are from employee personal use or that are outdated, distressed, misbranded, or adulterated.

21. On or about May 22, 2008, vials of Testosterone/Estradiol 50mg/2mg Injectable Solution lot 03200827@1 were sitting on a shelf with inadequate protection form light.

22. The compounded product contains Testorone Cypionate which requires protection from light.

23. On or about May 22, 2008, Specialty's compound logs listed a lot number that expiration had passed as the lot used for an ingredient in the compound.

| **Product** | **Lot Number** | **Compound** | **Ingredient** | **Ingredient** |
|---|---|---|---|---|

| | | date | | expiration date |
|---|---|---|---|---|
| Chlormabucil Suspension | 11200705@36 | 11/5/07 | Silica gel | 4/23/07 |
| Bi-Est | 11200705@13 | 11/5/07 | Magnesium Stearate | 9/12/05 |
| Nystatin Suspension | 11200705@12 | 11/5/07 | Stevia<br>Methylcellulose | 8/17/07<br>7/24/07 |
| Nystatin Suspension | 11200705@10 | 11/5/07 | Stevia<br>Methylcellulose | 8/17/07<br>7/24/07 |
| Psyllium/Senna | 11200705@05 | 11/5/07 | Oral Suspending Agent | 6/2/07 |
| Hydroquinone Cream | 11200702@8 | 11/2/07 | Vitamin E Oil | 8/26/07 |
| Piroxicam Suspension | 11200702@10 | 11/2/07 | Silica Gel in Oil | 4/23/07 |
| Fluconazole | 11200701@11 | 11/1/07 | Stevia<br>Acesulfame<br>Methylcellulose | 8/17/07<br>6/2/07<br>6/9/07 |
| Bi-Est | 10200731@8 | 10/31/07 | Estriol | 5/1/07 |
| Potassium Bromide | 10200731@11 | 10/31/07 | Preserved Water | 6/5/07 |
| Bi-Est | 10200730@14 | 10/30/07 | Estriol | 5/1/07 |
| Oxytetracycline/HC | 10200730@10 | 10/30/07 | Mineral Oil<br>Magnesium Stearate | 7/30/06<br>7/12/05 |
| HC/Polymyxin/ Oxytetracycline | 10200730@8 | 10/30/07 | Oxytetracycline/HC | 3/21/06 |
| Potassium Bromide | 10200731@11 | 10/31/07 | Preserved Water | 6/5/07 |
| Fluconazole | 11200701@11 | 11/1/07 | Stevia<br>Acesulfame<br>Methylcellulose | 8/17/07<br>3/20/07<br>6/9/07 |
| Piroxicam | 11200702@6 | 11/2/07 | Silica Gel | 4/23/07 |
| Orbifloxacin | 11200705@14 | 11/5/07 | Triple Fish Susp.<br>Bitterness Suppressor | 7/30/07<br>7/27/06 |
| Amlodipine | 11200705@25 | 11/5/07 | Triple Fish Susp.<br>Bitterness Suppressor | 7/30/07<br>7/27/06 |
| Nitroglycerin | 11200705@29 | 11/5/07 | Nitroglycerin<br>Petrolatum | 2/28/06<br>8/24/06 |
| Prednisone | 11200705@18 | 11/5/07 | Silica Gel | 4/23/07 |
| Methimazole | 11200705@24 | 11/5/07 | Triple Fish Susp. | 7/30/07 |
| Prednisone | 11200705@31 | 11/5/07 | Triple Fish Susp.<br>Bitterness Suppressor | 7/30/07<br>7/27/06 |
| Methimazole | 11200705@6 | 11/5/07 | Silica Gel | 4/23/07 |
| Piroxicam | 11200705@11 | 11/5/07 | Silica Gel | 4/23/07 |
| Budesonide | 11200705@2 | 11/5/07 | Triple Fish Susp.<br>Budesonide | 7/30/07<br>5/14/06 |
| Phenytoin | 11200702@19 | 11/2/07 | Phenytoin | 1/22/07 |

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|---|---|---|---|---|
| Misoprostol | | | Misoprostol | 6/16/06 |
| Ursodiol | 11200714@3 | 11/14/07 | Stevia<br>Hydroxyethylcellulose | 8/17/07<br>6/24/07 |
| Budesonide | 11200714@5 | 11/14/07 | Methylcellulose | 7/24/07 |
| Metronidazole | 11200709@2 | 11/9/07 | Triple Fish Susp. | 7/30/07 |
| Testosterone | 11200708@16 | 11/8/07 | Carbopol | 1/11/06 |
| Methimazole | 11200709@3 | 11/9/07 | Anhydrous PLO | 2/19/07 |
| Bi-Est | 11200709@7 | 11/9/07 | Estriol | 5/1/07 |
| Potassium Bromide | 11200709@8 | 11/9/07 | Preserved Water | 6/5/07 |
| Cisapride | 11200709@9 | 11/9/07 | Triple Fish Susp. | 7/30/07 |
| Ketoprofen<br>Lidocaine | 11200709@10 | 11/9/07 | Petrolatum | 8/24/06 |
| Potassium Bromide | 11200712@1 | 11/12/07 | Preserved Water | 6/5/07 |
| Thyroid | 11200712@4 | 11/12/07 | Thyroid | 1/27/04 |
| Methimazole | 11200708@14 | 11/8/07 | Silica Gel | 4/23/07 |
| Anesthetic Cream | 10200730@1 | 10/30/07 | Benzocaine | 8/20/05 |
| DHEA | 11200706@9 | 11/6/07 | Calcium Carbonate<br>Methocel | 10/28/07<br>4/20/06 |
| Amitriptyline | 11200708@11 | 11/8/07 | Purified Water<br>Poloxamer Base | 4/8/03<br>5/3/07 |
| Budesonide | 11200708@12 | 11/8/07 | Budesonide<br>Silica Gel | 5/14/06<br>4/23/07 |
| Amitriptyline | 11200708@18 | 11/8/07 | Purified Water<br>Poloxamer Base | 4/8/03<br>5/3/07 |
| Nystatin | 11200708@17 | 11/8/07 | Stevia<br>Methylcellulose | 8/17/07<br>7/24/07 |
| Amlodipine | 10200730@4 | 10/30/07 | Bitterness Suppressor<br>Triple Fish Susp. | 7/27/06<br>7/30/07 |
| DHEA | 10200729@19 | 10/29/07 | Calcium Carbonate | 10/28/07 |
| Phenobarbital | 10200730@7 | 10/30/07 | Methylcellulose | 7/24/07 |
| Potassium Bromide | 10200730@6 | 10/30/07 | Preserved Water | 6/5/07 |
| Diltiazem | 10200729@15 | 10/29/07 | Diltiazem<br>Poloxamer Base | 10/1/07<br>5/3/07 |
| Amlodipine | 10200730@11 | 10/30/07 | Triple Fish Susp.<br>Bitterness Suppressor | 7/30/07<br>7/27/06 |
| Diltiazem | 10299730@15 | 10/30/07 | Diltiazem<br>Poloxamer Base | 10/1/07<br>5/3/07 |
| Dexamethasone | 10200726@15 | 10/26/07 | Cherry Flavor | 7/23/04 |
| Dermazinc | 10200730@16 | 10/30/07 | Clobetasol | 9/30/07 |
| Fluconazole | 10200730@19 | 10/30/07 | Stevia<br>Acesulfame<br>Methylcellulose | 8/17/07<br>3/20/07<br>6/9/07 |
| Bi-Est | 10200730@17 | 10/30/07 | Estriol | 5/1/07 |
| Lisinopril | 10200731@5 | 10/31/07 | Methylcellulose | 7/24/07 |
| Mexiletine | 10200731@9 | 10/31/07 | Stevia | 8/17/07 |

| | | | | |
|---|---|---|---|---|
| | | | Hydroxyethylcellulose | 6/24/07 |
| Cyproheptadine | 10200731@10 | 10/31/07 | Cyproheptadine<br>Poloxamer Base | 5/31/07<br>5/3/07 |
| Cisapride | 11200701@1 | 11/1/07 | Triple Fish Susp. | 7/30/07 |
| Cyclobenzaprine | 10200731@12 | 10/31/07 | Poloxamer Base | 5/3/07 |
| Testosterone | 11200701@2 | 11/1/07 | Carbopol | 1/11/06 |
| Fluoxetine | 11200701@3 | 11/1/07 | Poloxamer Base | 5/3/07 |
| Phenoxybenzamine | 11200701@6 | 11/1/07 | Magnesium Stearate | 9/12/05 |
| Amlodipine | 11200701@5 | 11/1/07 | Poloxamer Base | 5/3/07 |
| Prednisolone | 11200701@10 | 11/1/07 | Triple Fish Susp. | 7/30/07 |
| Bi-Est | 11200701@8 | 11/1/07 | Estriol | 5/1/07 |
| Methimazole | 11200702@7 | 11/2/07 | Silica Gel | 4/23/07 |
| Doxycycline | 11200702@7 | 11/2/07 | Stevia<br>Silica Gel | 8/17/07<br>4/23/07 |
| Methimazole | 11200702@17 | 11/2/08 | Triple Fish Susp. | 7/30/07 |
| Anesthetic Cream | 10200730@5 | 10/30/07 | Benzocaine | 8/20/05 |
| Zinc Acetate | 10200726@8 | 10/26/07 | Magnesium Stearate | 9/12/05 |
| DHEA | 10200729@20 | 10/29/07 | Calcium Carbonate | 10/28/07 |
| Prednisolone | 11200702@14 | 11/2/07 | Triple Fish Susp. | 7/30/07 |
| Cisapride | 11200702@18 | 11/2/07 | Triple Fish Susp. | 7/30/07 |
| Budesonide | 04200804@8 | 4/4/08 | Methylcellulose | 11/10/07 |
| Azithromycin | 04200803@13 | 4/3/08 | Silica gel | 7/11/04 |
| Amitriptyline | 04200803@14 | 4/3/08 | Purified Water | 4/8/03 |
| Amitriptyline | 04200803@16 | 4/3/08 | Purified Water | 4/8/03 |
| Cisapride | 04200803@17 | 4/3/08 | Methylcellulose | 11/10/07 |
| Budesonide | 04200803@11 | 4/3/08 | Budesonide<br>Trituration | 5/14/06 |
| Nitroglycerin | 04200802@14 | 4/2/08 | Nitroglycerin | 2/28/06 |
| Amitriptyline | 04200801@11 | 4/1/08 | Purified water | 4/8/03 |
| Prednisolone | 10200731@2 | 10/31/07 | Triple Fish Susp. | 7/30/07 |

24. On or about May 22, 2008, Specialty's compound logs reflected that following compounded items were assigned a beyond-use date that exceeded the expiration date of the lot number recorded for at least one of the ingredients used.

25.

| **Product** | **Lot Number** | **Beyond Use Date** | **Ingredient** | **Ingredient expiration date** |
|---|---|---|---|---|
| Bi-Est | 11200705@13 | 5/3/08 | Methocel | 2/24/08 |

| | | | | |
|---|---|---|---|---|
| Oral Suspending Vehicle | 11200705@9 | 5/3/08 | Whey | 12/10/07 |
| Cyclosporine | 10200729@22 | 12/28/07 | Caprylic Triglycerides | 12/2/07 |
| Anesthetic Cream | 10200730@1 | 4/27/08 | Tetracaine<br>Propylene Glycol | 4/5/08<br>11/28/07 |
| Anesthetic Cream | 10200730@1 | 4/27/08 | Propylene Glycol<br>Tetracaine | 11/28/07<br>4/5/08 |
| DHEA | 10200729@19 | 4/26/08 | Methocel | 2/24/08 |
| Progesterone | 10200730@13 | 4/27/08 | Methocel | 2/24/08 |
| Anesthetic Cream | 10200730@5 | 4/27/08 | Tetracaine<br>Propylene Glycol | 4/5/08<br>11/28/07 |
| Zinc Acetate | 10200726@8 | 1/24/08 | Zinc Acetate | 12/29/07 |
| Benzocaine | 04200802@10 | 3/28/09 | Benzocaine<br>Polysorbate<br>Phenylephrine<br>Fragrance | 9/30/08<br>3/9/09<br>11/30/08<br>4/27/08 |
| Bi-Est | 04200801@4 | 9/28/08 | Methocel<br>Progesterone | 6/19/08<br>7/19/08 |
| Sodium Carboxymethylcelluose | 04200804@12 | 10/1/08 | Preserved Water | 4/8/08 |
| Amoxicillin/Clavunate | 04200804@5 | 5/4/08 | Silica | 4/17/08 |
| Bi-Est | 04200803@5 | 9/30/08 | Progesterone | 7/19/08 |
| Methimazole | 04200803@8 | 7/2/08 | Anhydrous PLO | 5/18/08 |
| Progesterone | 04200802@18 | 9/29/08 | Progesterone | 7/19/08 |
| Potassium Bromide | 04200802@6 | 9/29/08 | Preserved Water | 4/8/08 |
| Potassium Bromide | 04200801@15 | 9/28/08 | Preserved Water | 4/8/08 |
| Amitriptyline | 04200801@16 | 9/28/08 | Silica Gel | 4/17/08 |
| Estriol | 04200802@9 | 9/29/08 | Estriol Trituration | 7/25/08 |
| Progesterone | 04200801@6 | 9/28/08 | Progesterone | 7/19/08 |

26. On or about May 22, 2008, Specialty's compound logs for the following compound items did not reflect the lot number and/or expiration dates of at least one ingredient:

| Product | Lot Number | Compound date | Missing lot number | Missing expiration date |
|---|---|---|---|---|
| DHEA | 042000807@4 | 4/7/08 | X | X |
| Thyroid | 11200712@5 | 11/12/07 | X | X |
| Chlorambucil | 11200705@36 | 11/5/07 | | X |
| Orbifloxacin | 11200705@14 | 11/5/07 | X | X |
| Amlodipine | 11200705@25 | 11/5/07 | | X |
| Metronidazole | 11200709@2 | 11/9/07 | X | X |
| Benzocaine | 10200730@1 | 10/30/07 | X | |
| Sotalol | 10200730@18 | 10/30/07 | X | X |
| Dermazinc | 10200730@16 | 10/30/07 | X | |
| Mexiletine | 10200731@9 | 10/31/07 | | X |
| Nitroglycerin | 04200802@14 | 4/2/08 | X | |
| Alprostadil Papaverine Phentolamine | 05200806@19 | 5/6/2008 | X | X |
| Aprostadil | 04200817@27 | 4/17/08 | X | X |

27. On or about May 22, 2008 the only container of Magnesium Stearate NF (an inactive ingredient) in Specialty's inventory was labeled lot C105710 and bore an expiration date of September 12, 2005.

28. Specialty's computer records indicated that approximately 550 different items were compounded between September 12, 2005 and January 8, 2008 using lot C105710 of Magnesium Stearate NF as an ingredient.

29. Specialty compounded items with expired ingredients and/or did not maintain accurate logs and computer records regarding the ingredients used for compounded products.

30. Specialty compounded the following drugs using a drug ingredient provided by the customer:

| Product | Lot | Compound date |
|---|---|---|

| | | |
|---|---|---|
| Orbifloxacin | 11200705@14 | 11/5/07 |
| Lisinopril | 10200731@5 | 10/31/07 |

31. Orbifloxacin is an antibacterial drug for dogs and cats; Lisinopril is for humans.

32. On May 28, 2008 Specialty's drug inventory included the following vials that had not been distributed to Specialty by a licensed distributor, but were provided by the pet owner following purchase from a veterinarian by the pet owner.

| **Drug** | **Patient** | **Veterinarian** | **Date** |
|---|---|---|---|
| Tylan Powder | J.R16840 | Hause | 8/17/06 |
| Tylan Powder | W.C. 13387 | Hause | 10/29/07 |
| Tylan Powder | L.A.14301 | Hause | 9/27/07 |
| Tylan Powder | L. A. 14301 | Hause | 11/6/07 |
| Baytril | H.H | Kersting | 10/19/06 |

33. Tylan powder and Baytril are antibotics for dogs and cats.

34. Section 338.315, RSMo 2000, states in pertinent part:

> It shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs from other than a licensed or registered drug distributor or licensed pharmacy.

35. 20 CSR 2220-2.400 states in pertinent parts:

> (6) Proper controls shall be maintained over drug products/ingredients, containers and container closures.
>
> * * *
>
> (B) Pharmacists shall only receive, store or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors.
>
> * * *
>
> (D) Drug products/ingredients, containers and container closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination.

(E) Drug product/ingredient containers and container closures shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded drug beyond the desired result. Container systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;
2. Date of compounding;
3. Identity of the compounding pharmacist;
4. A listing of the drug products/ingredients and their amounts by weight or volume;
5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;
6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and
7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

* * *

(8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

1. Personnel are capable and qualified to perform their assigned duties;
2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards or maintain

a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;
3. Reasonable assurance that processes are always carried out as intended or specified;
4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and

* * *

Compounding of Commercially Available Products

36. Specialty compounded the following products for which there is a commercially available product and for which Specialty did not adequately document the medical reason the preparation was being compounded in that Specialty had a prescription form a physician to compound the drug, but the physician did not set forth medical reasons for compounding on the prescriptions:

| Rx Number | Date | Drug | Commercially-available |
|---|---|---|---|
| 149286 | 8/24/07 | DHEA 25mg capsule | Various Manufacturers |
| 154792 | 4/15/08 | DHEA 50mg capsule | Various Manufacturers |
| 146172 | 5/1/07 | Diltiazem 30mg capsule | Various Manufacturers |
| 152416 | 1/9/08 | Estradiol 0.5mg capsule | Various Manufacturers |
| 155130 | 4/30/08 | Fluconazole 100mg capsule | Various Manufacturers |
| 144734 | 3/7/07 | Guaifenesin 600mg capsule | Various Manufacturers |
| 155583 | 5/20/08 | Mebendazole 100mg capsule | Various Manufacturers |
| 149259 | 8/21/07 | Melatonin 1mg capsules | Various Manufacturers |
| 150605 | 10/15/07 | Nystatin 100,000u/ml Susp. | Various Manufacturers |
| 150953 | 10/29/07 | Progesterone 100mg capsule | Prometrium |
| 152804 | 1/24/08 | Progesterone 200mg | Prometrium |
| 148229 | 7/12/07 | Ranitidine 15mg/ml Syrup | Various Manufacturers |
| 153872 | 3/12/08 | Terbutaline 1mg/ml Soln. | Various Manufacturers |
| 151822 | 12/4/07 | Tri-iodothyronine (T3) 25 mcg capsule | Cytomel |
| 143241 | 1/24/07 | Tri-iodothyronine (T3) 5mcg capsule | Cytomel |
| 145846 | 4/23/07 | Niacin 500mg capsule | Various Manufacturers |
| 148546 | 7/25/07 | Lorazepam 2mg/ml Soln. | Various Manufacturers |
| 148771 | 8/20/07 | Melatonin 3mg capsule | Various Manufacturers |
| 147909 | 6/29/07 | Thyroid 120mg capsule | Various Manufacturers |

| | | | |
|---|---|---|---|
| 146329 | 5/7/07 | Thyroid 90mg capsule | Various Manufacturers |
| 148344 | 7/17/07 | DHEA 100mg Capsule | Various Manufacturers |

37. 20 CSR 2220-2.400(9) states:

> Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

Risk level 3 products

38. Specialty's sterile product compounding falls under the risk 3 category of 20 CSR 2220-2.200(11)(AA).3, as effective at all times material herein [currently 20 CSR 2220-2.200(1)(AA).3].

> Risk Level 3: Sterile products exhibit either characteristic A. or B."
>
> A. Products compounded from nonsterile ingredients or compounded with nonsterile components, containers or equipment before terminal sterilization.
>
> B. Products prepared by combining multiple ingredients (sterile and nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

39. 20 CSR 2220-2.200(22)(C) as effective at all times material herein [currently 20 CSR 2220-2.200(12)(C)], provides:

> Sterile products compounded from nonsterile components must be quarantined pending results of end-product testing.

40. 20 CSR 2220-2.200(22)(D), as effective at all times material herein [currently 20 CSR 2220-2.200(12)(D)], provides an exception for emergency dispensing, however, pursuant to 20 CSR 2220-2000(11)(O) [currently 20 CSR 2000(1)(O)]"the

prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record."

41. Specialty Pharmacy dispensed the following sterile products without documented prescriber authorization prior to end-product testing on the products:

| **Preparation** | **Lot #** | **Laboratory Dates** | **Rx #** | **Date dispensed** |
|---|---|---|---|---|
| Alprostadil | 04200817227 | Sterility/Endotoxin sample received by lab: 4/22/08 results reported: 5/6/08 | 149201 | 4/17/08 |
| Dexamethasone | 03200806@8 | Sterility/Endotoxin sample received by lab: 3/7/08 results reported: 3/24/08 | 146500 | 3/6/08 |
| Dexamethasone | 11200705@3 | Sterility/Endotoxin sample received by lab: 11/7/08 results reported: 11/21/07 | 143235<br>143361 | 11/1/07<br>11/5/07 |
| Alprostadil<br>Papaverine<br>Phentolamine | 05200806@19 | Sterility/Endotoxin sample received by lab: 5/9/08 results reported: 5/21/08 | 155270 | 5/6/08 |
| Dexamethasone | 05200819@23 | No lab results back from lab yet. | 155568 | 5/19/08 |
| Testosterone<br>Estradiol | 03200807@1 | Sterility/Endotoxin sample received by lab: 4/1/08 results reported: 4/15/08 | 154429 | 4/1/08 |

42. On or about May 22, 2008, Specialty could not produce endotoxin test results on lot 03200820@19 PAP/PHEN/PGE Injection compounded on March 20, 2008, or on lot 04200817@27 Alprostadil Injection compounded on April 17, 2008.

43. 20 CSR 2220-2.200(19) as in effect at all times material herein [currently 20 CSR 2220-2.200(9)] requires the maintenance of end-product evaluation and testing records be maintained and readily retrievable for a period of two years.

Validation of Beyond-Use Dates Beyond 30 Days

44. Specialty compounded the following risk level 3 sterile products with beyond-use dates beyond 30 days, for which the pharmacy did not verify potency and/or retain records documenting the verification of potency:

| **Product** | **Lot** | **Compound date** | **Test missing** |
|---|---|---|---|
| PAP/PHEN/PGE Injection | 03200820@19 | 3/20/08 | Endotoxin |
| Alprostadil Injection | 04200817@27 | 4/17/08 | Endotoxin |

45. 20 CSR 2.200(21)(C) as effective at all times material herein [currently 20 CSR 2220-2.200(11)(C)]states in pertinent part

> Products maintaining beyond-use dating of greater than (30) days shall have lab testing of product stability and potency.

46. 20 CSR 2.200(22)(C)(3)(D) as effective at all times material herein [currently 20 CSR 2220-2.200(12)(C)] states in pertinent part:

> The final potency is confirmed by instrumental analysis for sterile products that have been assigned a beyond-use date of more than (30) days.

47. 20 CSR 2.200(19)(C) as effective at all times material herein [currently 20 CSR 2220-2.200(9)©] states in pertinent part:

> (C) Risk Level 3: In addition to Risk Level 1 requirements, records of any end-product testing and batch preparation records must include:

* * *

4. End-product evaluation and testing records as required in section (22) . .

Compounding Without a Prescription

48. Between January 1, 2005 and June 25, 2008, a period of over 40 months, Specialty compounded and dispensed 27 products over-the counter, and not pursuant to a prescription. Of the 27 products, 22 were psyllium/senna flavorless powder, and all but one of those instances was for a single patient. Four of the products were for dogs for a clinical study conducted by a major pet care company in the region.

49. 20 CSR 2220-2.400(10) states in pertinent part:

> The compounding of any drug product to be sold without a prescription is prohibited.

Cause to Discipline

50. Section 338.210.5 states in pertinent part:

> 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

51. 20 CSR 2220-2.090 states in pertinent part:

> (2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:
>
> * * *
>
> (E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

* * *

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

* * *

(V) No outdated drugs are dispensed or maintained with the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

* * *

52. Section 338.285 states in pertinent part:

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

53. Cause exists to discipline both Ori's license as a pharmacist, and Specialty pharmacy permit pursuant to §338.055, RSMo, which in pertinent part, states as follows:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.

* * *

(13) Violation of any professional trust or confidence;

**Joint Agreed Disciplinary Orders**

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary orders entered by the Board in this matter under the authority of § 621.045.3, RSMo.

1. Specialty Pharmacy of St. Louis, LLC, license number 2002005329 is hereby placed on PROBATION for a period of three (3) years (the "disciplinary period"). However, in lieu of serving the discipline imposed by this order, and it light of Specialty Pharmacy of St. Louis, LLC having ceased operations, Specialty Pharmacy of St. Louis, LLC elects to surrender its license as a pharmacy.

2. Ori's pharmacist license, license number 2000148445 is hereby placed on PROBATION for a period of three (3) years (the "disciplinary period") beginning January 1, 2012. During the disciplinary period, Ori shall abide by the following terms and conditions:

A. Ori shall keep the Board apprised of his current home and work addresses and telephone numbers. If at any time Ori is employed by a temporary employment agency or maintains employment that requires frequent daily or

weekly changes of work locations he must provide the Board of list of locations worked if requested by the Board or Board's representative.

B. Ori shall pay all required fees for licensing to the Board and shall renew his license prior to October 31 of each licensing year.

C. Ori shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

D. Ori shall make himself available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Ori will be notified and given sufficient time to arrange these meetings.

E. If, after disciplinary sanctions have been imposed, the Ori ceases to keep his Missouri license current or fails to keep the Board advised of his current place of employment and residence, such periods shall not be deemed or taken as any part of the time of discipline so imposed.

F. If, after disciplinary sanctions have been imposed, the Ori begins employment as a pharmacist or technician outside the State of Missouri, such periods shall not be deemed or taken as any part of the time of discipline so imposed. Ori may petition the Board to seek a waiver for any portion of this requirement by making such a request in written form to the Board for its

consideration. No exception will be made to this requirement without prior Board approval.

G. If Ori leaves the State of Missouri for more than 30 consecutive days, such periods shall not be included as a part of the time of discipline so imposed.

H. Ori shall provide all current and future pharmacy and drug distributor employers and pharmacist/manager-in-charges a copy of this disciplinary order/agreement within five (5) business days of the effective date of discipline or the beginning date of each employment. If at any time Ori is employed by a temporary employment agency he must provide each pharmacy and drug distributor employer and pharmacist/manager-in-charge a copy of this disciplinary order/agreement prior to or at the time of any scheduled work assignments.

I. Ori shall not serve as a preceptor for interns.

J. Ori shall report to the Board, on a preprinted form supplied by the Board office, once every six months (due by each January 1 and July 1), beginning with whichever date occurs first after this Order/Agreement becomes effective, stating truthfully whether or not he has complied with all terms and conditions of his/her disciplinary order.

K. Ori shall not serve as a pharmacist-in-charge or in a supervisory capacity without prior approval of the Board.

L. Ori shall take and pass the Board's designated jurisprudence (law) examination within 180 days of the beginning of probation. Ori shall register to take the Multistate Pharmacy Jurisprudence Examination (MPJE) e National Association of Boards of Pharmacy (NABP) website, www.nabp.net, no less than ninety (90) days prior to the date Ori desires to take the examination. Ori shall complete the registration materials and submit them and the required fee to NABP. If Ori is unable to obtain the registration materials online, Ori shall contact the NABP office for the required registration materials. Upon Ori's receipt of an Authorization to Test (ATT), Ori shall schedule the exam as instructed. If necessary, Ori will be given three opportunities to take and pass the examination. To prepare for the examination, Ori shall access the Board's website to review the laws and regulations. The Ori will bear all cost involved in taking the examination.

**Further Provisions**

1. Ori'sfailure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order/Agreement.

2. The parties to this settlement agreement understand that the Board of Pharmacy will maintain this settlement agreement as an open record of the Board as provided in Chapters 338, 610, and 324 RSMo.

3. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated,

except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

4. Ori and Specialty Pharmacy of St. Louis, LLC hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to 536.087, RSMo, or any claim arising under 42 U.S.C. 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

5. This settlement agreement goes into effect fifteen (15) days after the document is signed by the Executive Director of the Board.

LICENSEES

09-02-11
LEE ORI Date

SPECIALTY PHARMACY OF ST. LOUIS, LLC

by 09-02-11

MISSOURI STATE BOARD OF PHARMACY

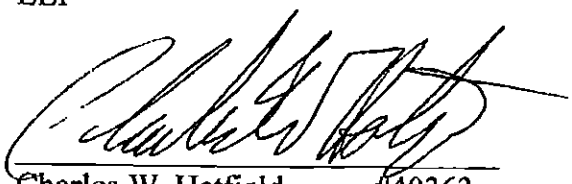
Kimberly Grinston
Executive Director

Date 9/7/11

Date

Title_____

STINSON MORRISSON HECKER, LLP



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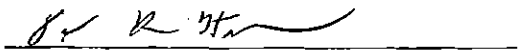

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